UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,584	12/21/2001	Craig A. Rosen	PF112P1D2	4809

22195 7590 11/26/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,584	ROSEN ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- Th MAILING DATE of this communication appears n the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 8/22/03

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-110 is/are pending in the application.

4a) Of the above claim(s) 6, 7, 11-21, 27, 28, 38, 39, 43-51, 67, 68, 80-96 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5, 8-10, 22-26, 29-37, 40-42, 52-66, 69-79 and 97-110 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 12/21/01
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/12/02
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Claims 1-110 were pending in the application and were subject to restriction in the Office Action mailed 7/24/03. Applicants elected, with traverse, Group I, and the specific fragment which binds amino acids –46-373 of SEQ ID NO:2. Since SEQ ID NO:2 is encoded by ATCC Deposit No. 97149, Groups I and III will be rejoined. The Examiner will also search residues –46 to 373; -23 to 373; 1 to 373 and 24 to 373 of SEQ ID NO:2. A response to Applicants' arguments regarding the rejoinder of the product claims with the method of using the product is seen below.

2. Traversal

A. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Regarding the election of residues –46 to 373 of SEQ ID NO:2, Applicants argue that the other sequences are found in this sequence and a search of the large sequence will encompass a search of the smaller sequences. This is not the case. An antibody which binds to residues 1-24 of SEQ ID NO:2 will not necessarily bind to residues 108-121 of SEQ ID NO:2. Therefore, a search for one antibody will not necessarily overlap the search for the other antibodies. This is why a restriction was made, and not a species election. However, the Examiner will search residues –46 to 373; -23 to 373; 1 to 373 and 24 to 373. Therefore, claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66, 69-89 and 97-110 are the subject of this Office Action. This restriction is deemed proper and is made FINAL.

3. Information Disclosure Statement

A. Applications 08/340,011; 08/510,133; 08/585,895; 08/601,132; 08/671,573; 60/003,491 and 08/554,374 on the IDS filed 12/21/01, have been lined through. Applications 08/340,011; 08/510,133; 08/585,895; 08/601,132 have issued as patents and the Examiner has placed these references on a Form PTO-892. However, application 60/003,491 is owned by Genentech, not HGS. Similarly, 08/554,374 is owned by Immunex. Therefore, these applications have been considered, but will not be published as part of the IDS.

B. References AF-AM and AU-BS have been lined through since the citations are incomplete. No International country code has been included. It is not clear if these are, for example, WO documents or PCTs since the references were not provided with the present application.

C. Reference FR on the IDS filed 12/21/01, has been lined through since it the WO document has an extra digit in the patent number, though it is not clear which number is incorrect.

D. References DW (Litwin et al.) and EB (Walsh et al.) on the IDS filed 12/21/01 have been lined through since the publication date has not been provided.

E. References FT and FU on the IDS filed 12/21/01 and reference FW on the IDS filed 3/12/02 have been lined through since International Search Reports are not proper subject matter for an IDS. The references on this report should be listed individually.

4. Interference

A. Applicants have added new claims 97-110 specifically for the purpose of provoking an interference with 6,403,088 (Alitalo et al.). Applicants state in the response filed 5/7/03 that some or all of the claims 1-110 correspond exactly or substantially to claims 1-6 of Alitalo. This issue will be considered when the present claims are found allowable.

5. Specification

A. The specification is objected to since neither Figure 1, nor its Brief Description, is identified by SEQ ID NO. Furthermore, Figures 1A – 1D recite "match with Figure..." It is suggested that this phrase be removed from the Figures.

B. The specification is objected to since the priority data in the first line of the specification should be updated to recite whether the parent applications are abandoned, or allowed. If they are allowed, the patent number should be recited.

C. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are drawn to antibodies the VEGF receptor.

6. Claim Rejections - 35 USC § 112, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 52-66, 69-89 and 97-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of the biological material is considered necessary for the enablement of the current invention (see MPEP Chapter 2400 and 37 C.F.R. §§ 1.801-1.809). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If a deposit (NRRL Y-15851) is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent

Procedure (e.g. see 961 OG 21, 1977), and Applicants, their assignee or their agent needs to provide a declaration containing the following:

1. the current address of the ATCC.
2. a declaration, or statement over attorney's signature stating that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent (see MPEP Chapter 2410.01 and 37 C.F.R. § 1.808).

B. Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66 and 69-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims recite "specifically binds." It is not understood how Applicants can make a protein which binds to only the desired peptide and to no other peptides. Applicants provide no guidance or working examples of these antibodies, nor is it predictable to one of ordinary skill in the art how to make an antibody which "specifically binds" the proteins of the present invention and to no others. Therefore, the Examiner has concluded that undue experimentation is required to practice the invention as claimed.

C. Claims 52, 54, 58-66, 69, 71, 74-76, 78, 82-89 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims recite antibodies which bind the "**mature**" form of VEGF-2. However, Applicants have not provided any guidance or working examples of the "mature" form of the VEGF-2 of the present invention. The exact sequence of any mature form has not been disclosed in the specification. Furthermore, it is not predictable to the artisan what would be the sequence of the mature form of the polypeptide.

D. Claims 98, 100, 106 and 108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims recite "pharmaceutically acceptable carrier." Applicants have provided no guidance or working examples of the use of these antibodies for any pharmaceutical purpose, nor would it be predictable to the artisan how to use these antibodies, including for what diseases to treat. Applicants could overcome this rejection by amending the claim to recite, for example, "inert carrier" as long as no new matter is added. Furthermore, amending the claims as such, or simply to "carrier" would broaden the claims, since this limitation would encompass pharmaceutically acceptable carriers.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 52, 54, 58-66, 69, 71, 74-76, 78, 82-89 and 97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims recite a "mature form of the polypeptide." However, the instant specification fails to describe that portion of a protein which is the "mature" portion. Applicant is claiming a very specific species which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature portion of a protein" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved in vivo, as well as being differentially processed based on which in tissue the protein is expressed. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of the "mature portion of a protein", therefore, the specification does not provide an adequate written description of a mature protein, and thus the claimed invention, to the extent that it reads upon mature protein was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66 and 69-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the term "specifically binds." However, the metes and bounds of this term are not known. It appears from this term that Applicants desire the production of an antibody which binds to the desired proteins and to no other proteins.

9. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66, 69-89 and 97-110 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of at least claim 19 of copending Application No. 09/499,468; claim 14 of copending Application No. 10/060,523; claim 20 of copending Application No. 10/120,398; claim 21 of copending Application No. 10/120,377 and claim 21 of copending Application No. 10/120,414 This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 24, 2003